

Clinical Study Results

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study medication works, how it works, and if it is safe to prescribe to patients. The results of this study might be different than the results of other studies that the researchers review.

Sponsor: Pfizer Inc.

Medicine(s) Studied: Etrasimod (PF-07915503, APD334)

Protocol Number: C5041007

Dates of Study: 10 September 2021 to 06 October 2023

Title of this Study: A Study to Look at Whether Etrasimod Improves Ulcerative Colitis Symptoms and Whether it is Safe After 12-weeks of Treatment in Japanese Participants.
[A Phase 2, Randomized, Double-Blind, Placebo-Controlled, 12-Week Dose-Ranging Study to Assess the Efficacy and Safety of Etrasimod in Japanese Participants with Moderately to Severely Active Ulcerative Colitis]

Date(s) of this Report: 27 May 2024

– Thank You –



If you participated in this study, Pfizer, the Sponsor, would like to thank you for your participation.

This summary will describe the study results. If you have any questions about the study or the results, please contact the doctor or staff at your study site.

Why was this study done?

What is ulcerative colitis?

Ulcerative colitis causes pain, swelling, and redness (inflammation) of part of the bowel or large intestine called the colon. It is caused by an over-reaction of the immune system (the body's defense system, which fights infection). People with ulcerative colitis experience occasional periods of increased inflammation, known as active disease or flares. The most common symptoms of ulcerative colitis are diarrhea, bloody stools, and fever. Active disease is often followed by periods of remission (time with no symptoms and healing of the colon lining) that vary in length from weeks to years.

What is etrasimod?

Etrasimod (et-ras-i-mod) is a tablet that is swallowed that researchers think may help reduce inflammation in the colon. It works by blocking the movement of a certain type of cells in the body to areas of inflammation in the colon. These cells are lymphocytes and are part of the immune system.

What was the purpose of this study?

The purpose of this study was to find out if etrasimod improves symptoms of ulcerative colitis.

Researchers wanted to know:

Did the participants taking etrasimod have no ulcerative colitis symptoms at Week 12?

What happened during the study?

How was the study done?

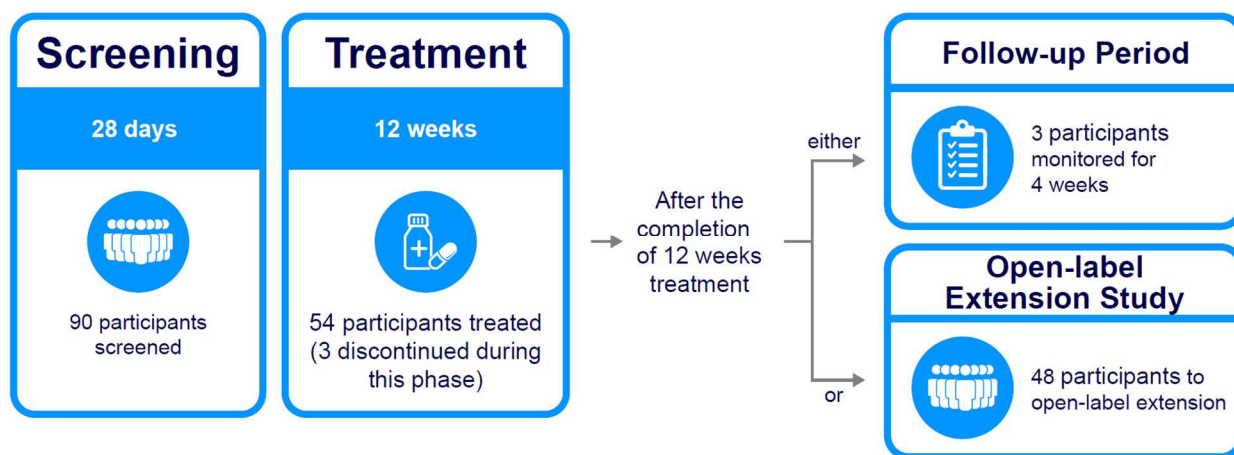
Researchers tested etrasimod on a group of study participants to find out if study participants taking etrasimod (the test medicine) had fewer ulcerative colitis symptoms than before they started the study and if their colon completely or partially healed. This is called clinical remission. Two doses of etrasimod were tested during this study, 1 mg or 2 mg.

Researchers then compared the results of study participants taking the study medication to the results of study participants taking a placebo. A placebo does not have any medicine in it, but it looks just like the study medication.

The study participants and researchers did not know who took etrasimod and who took the placebo. This is known as a “blinded” study. Study participants were assigned to each group by chance alone. There was an equal chance of getting etrasimod 1 mg, etrasimod 2 mg, or placebo.

Participants first went through a screening period, where the researchers assessed whether they were suitable for the study. If they were accepted into the study, they then entered a treatment period, where they took a tablet containing either etrasimod 1 mg, etrasimod 2 mg, or placebo every day. The treatment period lasted for 12 weeks. At the end of the treatment period, the participants had a series of tests and procedures, and then had 2 choices. If they wanted to, and had passed all additional tests, they could continue treatment in an open-label extension study. In the open-label extension study, all participants would be given etrasimod including participants who were previously given placebo. Alternatively, they could have 4 weeks of additional monitoring and finish the study.

Figure 1. Study Design



Where did this study take place?

The Sponsor ran this study at 48 locations in Japan.

When did this study take place?

It began on 10 September 2021 and ended 06 October 2023.

Who participated in this study?

The study included participants who met the inclusion/exclusion criteria for things such as age, condition type, severity, and prior treatments.

- A total of 35 men participated
- A total of 19 women participated
- All participants were between the ages of 20 and 72

Participants were to be treated until the end of the Week 12 treatment period. Of the 54 participants who started the study, 51 finished.

Three participants did not finish the study treatment because of medical problems (2 participants taking placebo) and personal reasons

(1 participant taking etrasimod 1 mg). These 3 participants left before the study was over by their choice or a doctor decided it was best for a participant to stop being in the study.

How long did the study last?

Study participants were in the study for up to 20 weeks. The entire study took 2 years to complete.

When the study ended in October 2023, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

What were the results of the study?

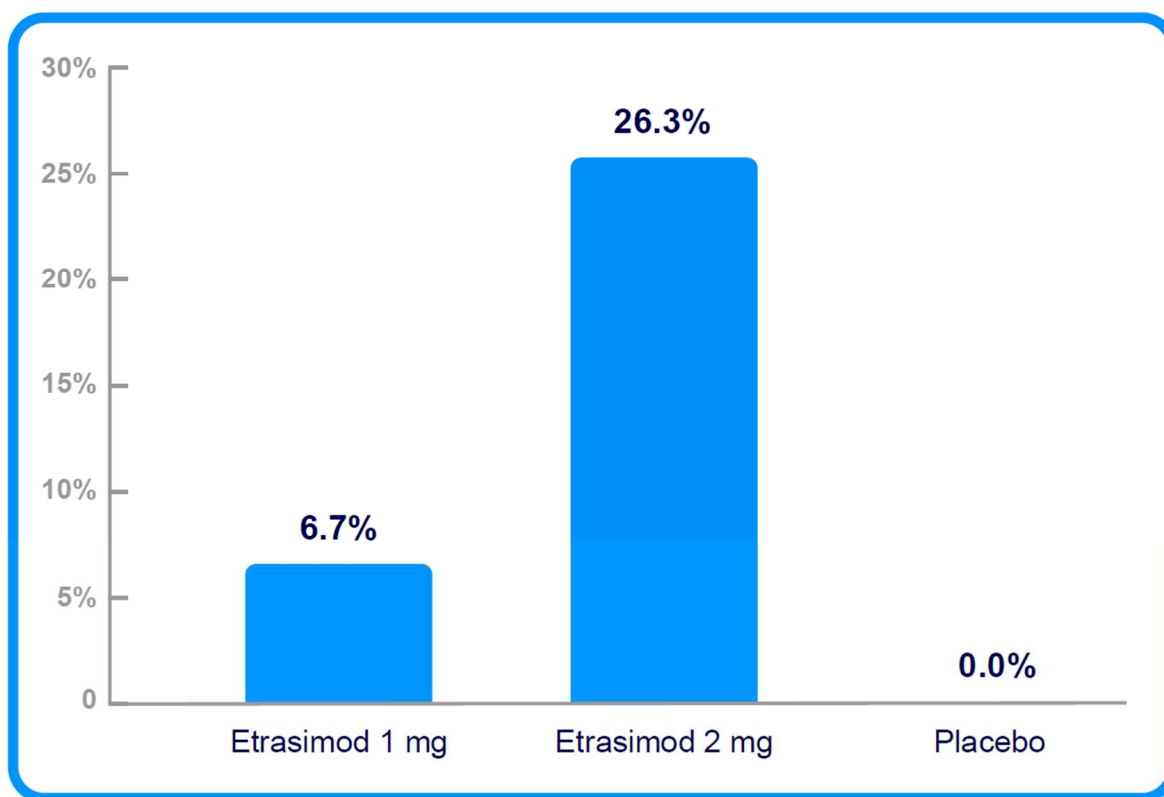
Did the participants taking etrasimod have no ulcerative colitis symptoms at Week 12?

Did the study medication help reduce symptoms and inflammation in colon in participants with ulcerative colitis compared to placebo?

One out of 15 (6.7%) participants who took etrasimod 1 mg were in remission at Week 12, while 5 out of 19 (26.3%) participants who took etrasimod 2 mg were in remission at Week 12. None of the participants taking placebo were in remission at Week 12. This is shown in Figure 2.

This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies may have different results.

Figure 2. Percentage of Participants in Remission



What medical problems did participants have during the study?

The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for example, caused by an underlying disease or by chance). Or, medical problems could also have been caused by a study treatment or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many treatment groups in many studies, doctors

try to understand what effects a study medication might have on a participant.

There were 32 out of 54 (59.3%) participants in this study who had at least 1 medical problem. A total of 2 participants left the study because of medical problems, both had been taking placebo. The most common medical problems – those reported by 2 or more participants – are described below.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists medical problems that were commonly reported during the study. All medical problems reported by 2 or more participants are listed.
- The **2nd** column tells how many of the 17 participants taking etrasimod 1 mg reported each medical problem. Next to this number is the percentage of the 17 participants taking etrasimod 1 mg who reported the medical problem.
- The **3rd** column tells how many of the 19 participants taking etrasimod 2 mg reported each medical problem. Next to this number is the percentage of the 19 participants taking etrasimod 2 mg who reported the medical problem.
- The **4th** column tells how many of the 18 participants taking placebo reported each medical problem. Next to this number is the percentage of the 18 participants taking placebo who reported the medical problem.
- Using these instructions, you can see that 3 out of the 18 (16.7%) participants taking placebo reported ulcerative

colitis. No participants taking 1 mg or 2 mg etrasimod reported ulcerative colitis.

Table 1. Commonly reported medical problems by study participants

Medical Problem	Etrasimod 1 mg (17 Participants)	Etrasimod 2 mg (19 Participants)	Placebo/ (18 Participants)
Mouth pain or sores	2 out of 17 participants (11.8%)	0 out of 19 participants	0 out of 18 participants
Ulcerative colitis	0 out of 17 participants	0 out of 19 participants	3 out of 18 participants (16.7%)
Feeling sick	1 out of 17 participants (5.9%)	0 out of 19 participants	1 out of 18 participants (5.6%)
COVID-19	0 out of 17 participants	1 out of 19 participants (5.3%)	1 out of 18 participants (5.6%)
Common cold	0 out of 17 participants	1 out of 19 participants (5.3%)	1 out of 18 participants (5.6%)

Table 1. Commonly reported medical problems by study participants

Medical Problem	Etrasimod 1 mg (17 Participants)	Etrasimod 2 mg (19 Participants)	Placebo/ (18 Participants)
Decreased red blood cell count	0 out of 17 participants	1 out of 19 participants (5.3%)	1 out of 18 participants (5.6%)

Did study participants have any serious medical problems?

A medical problem is considered “serious” when it is life-threatening, needs hospital care, or causes lasting problems.

There were no serious medical problems during this study.

No participants died during the study.

Where can I learn more about this study?

If you have questions about the results of your study, please speak with the doctor or staff at your study site.

For more details on your study protocol, please visit:

www.pfizer.com/research/

[research_clinical_trials/trial_results](http://www.pfizer.com/research/research_clinical_trials/trial_results)

Use the protocol number

C5041007

The full scientific report of this study is available online at:

www.clinicaltrials.gov

Use the study identifier

NCT05061446

Please remember that researchers look at the results of many studies to find out which medicines can work and are safe for patients.

Again, if you participated in this study,
thank you for volunteering.

We do research to try to find the
best ways to help patients, and you
helped us to do that!